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(54) Title: APPARATUS AND METHODS FOR TREATING CONGESTIVE HEART DISEASE

(57) Abstract

Methods and apparatus are provided for treating congestive heart failure using a catheter having an inlet end configured for placement in the source of arterial blood such as the aorta, left ventricle or a femoral artery, and an outlet end having at least one conduit configured to be placed in the renal arteries. The catheter includes a lumen through which blood passes from the aorta or left ventricle directly to the renal artery, means for engaging the first conduit with renal artery. The means for engaging also may reduce backflow of blood into the abdominal aorta. The catheter preferably is configured to permit percutaneous, transluminal implantation. Methods of using and implanting the catheter are also provided.

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APPARATUS AND METHODS FOR TREATING CONGESTIVE HEART DISEASE

Field Of The Invention

The present invention relates to apparatus for treating congestive heart disease by providing increased perfusion to the kidneys, thereby enhancing renal function.

Background Of The Invention

It has long been known that cardiac dysfunction induces a series of events that ultimately contribute to congestive heart failure ("CHF"). One such event is a reduction in renal blood flow due to reduced cardiac output. This reduced flow can in turn result in the retention of excess fluid in the patient's body, leading for example, to pulmonary and cardiac edema.

Chapter 62 of Heart Disease: A Textbook of Cardiovascular Medicine, (E. Braunwald, ed., 5th ed. 1996), published by Saunders, Philadelphia, Pennsylvania, reports that for patients with CHF, the fall in effective renal blood flow is proportional to the reduction in cardiac output. Renal blood flow in normal patients in an age range of 20-80 years averages 600 to 660 ml/min/m^2, corresponding to about 14 to 20 percent of simultaneously measured cardiac output. Within a wide spectrum of CHF severity, renal blood flow is depressed to an average range of 250 to 450 ml/min/m^2.

Previously known methods of treating congestive heart failure and deteriorating renal function in patients having CHF principally involve administering drugs, including diuretics that enhance renal function, such as furosemide and thiazide, vasopressors intended to enhance renal blood flow, such as Dopamine, and vasodilators that reduce vasoconstriction of the renal vessels. Many of these drugs, when administered in systemic doses, have undesirable side-effects.

In addition, for patients with severe CHF (e.g., those awaiting heart transplant), mechanical methods, such as hemodialysis or left ventricular assist devices, may be implemented. Mechanical treatments, such as hemodialysis, however, generally have not been used for long-term management of CHF.

Advanced heart failure (''HF'') requires the combination of potent diuretics and severe restriction of salt intake. Poor patient compliance is a major cause of refractoriness to treatment. On the other hand, as renal urine output decreases with reduced renal perfusion, in the event of dehydration, the required diuretic dosages increase.

In view of the foregoing, it would be desirable to provide methods and apparatus for treating and managing CHF without administering high doses of drugs or dehydrating the patient.

It further would be desirable to provide methods and apparatus for treating and managing CHF by improving blood flow to the kidneys, thereby enhancing renal function.

It also would be desirable to provide methods and apparatus for treating and managing CHF that permit the administration of low doses of drugs, in a localized manner, to improve renal function.

It still further would be desirable to provide methods and apparatus for treating and managing CHF using apparatus that may be percutaneously and transluminally implanted in the patient.

Summary of The Invention

In view of the foregoing, it is an object of the present invention to provide methods and apparatus for treating and managing CHF without administering high doses of drugs or dehydrating the patient.

It is another object of this invention to provide methods and apparatus for treating and managing CHF by improving blood flow to the kidneys, thereby enhancing renal function.

It is also an object of this invention to provide methods and apparatus for treating and managing CHF that permit the administration of low doses of drugs; in a localized manner, to improve renal function.

It further is an object of the present invention to provide methods and apparatus for treating and managing CHF using apparatus that may be percutaneously and transluminally implanted in the patient.

These and other objects of the present invention are accomplished by providing a catheter having an inlet end configured for placement in a source of arterial blood, such as the aorta, the left ventricle or a femoral artery, and an outlet end having at least one conduit configured to be placed in a renal artery. The catheter includes a lumen through which arterial blood passes directly into a renal artery. The conduit may include means for engaging an interior surface of the renal artery to retain the conduit in position, and may comprise an occluder that reduces backflow of blood exiting the conduit into the abdominal aorta. The catheter preferably is configured to permit percutaneous, transluminal implantation.

In accordance with the principles of the present invention, high pressure blood passes through the lumen of the catheter during systole and into the conduit disposed in the renal artery. It is expected that blood passing through the catheter will have a higher pressure and higher flow rate than blood reaching the renal artery via the abdominal aorta. This in turn is expected to improve renal function, without administering systemic doses of drugs to improve renal function or renal blood flow. The enhanced renal blood flow is expected to provide a proportional increase in renal function, thereby reducing fluid retention.

In alternative embodiments, the catheter may include first and second conduits for perfusing both kidneys, a one-way valve disposed in the lumen to prevent backflow of blood in the lumen during diastole or a mechanical pump to further enhance the flow of blood through the lumen. Still other embodiments of the catheter may include a drug infusion reservoir that injects a low dose of a drug, e.g., a diuretic or vasodilator, into blood flowing through the

lumen, so that the drug-infused blood passes directly into the kidneys. Still further embodiments may comprise separate catheters to perfuse the left and right kidneys, or may draw arterial blood from a peripheral vessel using an external pump.

Methods of implanting the apparatus of the present invention also are provided.

Brief Description Of The Drawings

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

FIG. 1 is a partial sectional view of a human circulatory system having apparatus constructed in accordance with the present invention implanted therein;

FIG. 2 is a side view of an illustrative embodiment of the apparatus of the present invention;

FIG. 3 is an alternative embodiment of the apparatus of FIG. 2 including a one-way valve, a blood pump and a drug infusion device;

FIG. 4 is a detailed perspective view of an occluder employed on the outlet end of the catheter of FIG. 2; and

FIGS. 5A and 5B are partial sectional views depicting an illustrative method of implanting the catheter of FIG. 2.

Detailed Description Of The Invention

The present invention provides a catheter that may be implanted in patients suffering from congestive heart failure ("CHF") to improve renal blood flow and renal function. In accordance with the principles of the present invention, it is expected that by passing blood from the left ventricle directly to the renal arteries during systole, the blood pressure and flow rate in the kidneys will be increased, resulting in enhanced renal function.

Referring to FIGS. 1 and 2, a first illustrative embodiment of apparatus constructed in accordance with the principles of the present invention is described. Catheter 10 comprises hollow flexible tube having inlet end 11 and outlet end 12. Inlet end 11 includes distal hole 13 and lateral holes 14 that communicate with lumen 15 within catheter 10. Outlet end 12 comprises first and second branch conduits 16 and 17, respectively. Catheter 10 preferably comprises a flexible biocompatible material, such as polyurethane, silicone, or polyethylene.

First branch conduit 16 includes outlet port 18 that communicates with lumen 15, and expandable occluder 19. Likewise, second branch conduit 17 includes outlet port 20 that communicates with lumen 15, and expandable occluder 21. First and second branch conduits 16 and 17 optionally may include radio-opaque marker bands 22 near outlet ports 18 and 20, respectively, to assist in implanting catheter 10.

As depicted in FIG. 1, catheter 10 is implanted in circulatory system C so that inlet end 11 is disposed in left ventricle LV or in the vicinity of aortic root AR, while first and second branch conduits 16 and 17, respectively, are disposed in renal arteries RA. Occluders 19 and 21, described in greater detail hereinafter, engage the walls of the renal arteries and retain first and second branch conduits 16 and 17, respectively in position. The occluders also serve to prevent backflow of high pressure blood exiting through outlet ports 18 and 20 from flowing backwards into abdominal aorta AA. Accordingly, blood entering catheter 10 via distal hole 13 and lateral holes 14 during systole passes directly into renal arteries RA and kidneys K through lumen 15, thereby enhancing renal blood flow and renal function.

Referring now to FIG. 3, an alternative embodiment of the apparatus of the present invention is described. Catheter 30 is similar in construction to catheter 10 of FIG. 1, and includes hollow flexible tube having inlet end 31 and outlet end 32. Inlet end 31 includes distal hole 33 and lateral holes 34 that communicate with lumen 35. Outlet end 32 comprises branch conduit 36 having outlet port 37 configured to be placed in one of the patient's renal arteries. In this

embodiment, the occluder of the embodiment of FIG. 2 is omitted and instead the diameter of the branch conduit 36 is selected to provide a close fit with the renal artery. Engagement means, such as small ribs or barbs 38 also may be disposed on the exterior surface of branch conduit 36 to retain the branch conduit in the renal artery.

Because the renal arteries may branch from the abdominal aorta at different levels, the catheter of FIG. 3 advantageously permits separate catheters to be used to each perfuse only a single kidney. In addition, the inlet end of catheter 30 may be configured to be placed in a peripheral vessel rather than the left ventricle.

Catheter 30 further optionally comprises any one or more of the following components: one-way valve 42, blood pump 43 or drug infusion device 44. While catheter 30 illustratively includes all three of the foregoing components, it is to be understood that any combination of such components advantageously may be employed.

One-way valve 42, if provided, is configured to open during systole to permit blood to flow through lumen 35 from left ventricle **LV** towards the renal artery **RA**, but closes during diastole to prevent the left ventricle from drawing blood in the opposite direction.

Blood pump 43, if provided, may comprise an implantable blood pump, such as are known in the art, and serves to enhance renal blood flow in those patients suffering from severe cardiac dysfunction. Alternatively, where the inlet end of catheter 30 is configured to be placed in a peripheral vessel, blood pump 30 advantageously may comprise an external blood pump, such as are known in the art.

Drug infusion device 44, if provided, preferably comprises an implantable infusion device, such as are known in the art (e.g., for chelation therapy), and periodically infuses low doses of therapeutic agents into blood flowing through lumen 35. Because the infused drugs are delivered directly into

the kidneys, smaller doses may be employed, while achieving enhanced therapeutic action and fewer side-effects.

With respect to FIG. 4, an illustrative embodiment of occluder 50 suitable for use with the catheter of FIGS. 1 and 2 is described. In one embodiment, occluder 50 comprises a low density, biocompatible sponge-like material that may be compressed to a small thickness, and that absorbs and expands when exposed to body fluid. In particular, occluder 50 preferably is compressed to a small thickness and then mounted on the branch conduit so that, when the occluder is deployed in a renal artery, it swells and engages the interior of the renal artery.

Occluder 50 therefore serves to retain the branch conduit in position in a renal artery, and also reduces backflow of blood from the renal artery into the abdominal aorta. Alternatively, occluder 50 may comprise an inflatable member that is inflated and then sealed via a lumen (not shown) extending out of the patient's femoral artery. As a yet further alternative, occluder 50 may comprise a self expanding hydrogel material that swells when exposed to body fluids to accomplish the functions described hereinabove.

While occluder 50 of FIG. 4 illustratively has an annular shape, it should be understood that other shapes may be employed. For example, occluder 50 may be configured to only partially surround the branch conduit, and may provide only a partial seal with the interior surface of the renal artery. For example, depending upon the relative sizes of the branch conduit and the renal artery, and how far the branch conduit extends into the renal artery, occluder 50 may be omitted altogether.

Referring now to FIGS. 1, 5A and 5B, percutaneous, transluminal implantation of the apparatus of FIG. 2 is described. First, guidewire 100 is inserted in a retrograde manner through abdominal aorta AA via an access site in femoral artery FA until the tip of the guidewire is disposed in the left ventricle, e.g., as determined by fluoroscopy. Catheter 10 is then advanced along guidewire 100, for example, using a push tube (not shown) disposed on guidewire 100, with

first and second branch conduits 16 and 17 folded side-by-side. Filament 110 is looped through a small opening at the bifurcation of the first and second branch conduits 16 and 17, so that the free ends 110a and 110b of loop 110 may be manipulated by the surgeon.

As depicted in FIG. 5A, catheter 10 is pushed in a distal direction so that outlet ports 18 and 20 of outlet end 12 clear the renal arteries, and guidewire 100 is withdrawn. Filament 110 then is pulled in the proximal direction so that the ends of the first and second branch conduits move into renal arteries **RA**, as illustrated in FIG. 5B. Strand 55 of an elastic, high strength material, such as a nickel-titanium alloy, may be embedded in the wall of catheter 10 in the bifurcation to ensure that the first and second conduits open outwardly when catheter 10 is pulled in a proximal direction by filament 110.

Once the position of first and second branch conduits 16 and 17 is confirmed, for example, by observing the location of radio-opaque markers 22 (see FIG. 2) with a fluoroscope, occluders 19 and 21 expand to engage the interior surfaces of the renal arteries. Expansion of the occluders may be accomplished either by holding the occluders in place while they expand (if self-expanding) or, if the occluders are inflatable, by injecting a suitable inflation medium.

Filament 110 then may be pulled completely through the opening in the bifurcation of catheter 10, leaving catheter 10 implanted in position. It is expected that the opening needed to accommodate filament 110 will result in negligible loss of blood through the opening once filament 110 has been withdrawn. Alternatively, or in addition, additional guidewires (not shown) may be disposed through first and second branch conduits to assist in placing the first and second branch conduits in renal arteries **RA**.

The foregoing methods may be readily adapted to implant two catheters of the type illustrated in FIG. 3, so that the branch conduit of each catheter perfuses a separate kidney. In addition, for acute treatment of CHF, the catheter of FIG. 3 (including an external blood pump) may be placed so that the

inlet end is disposed in a patient's femoral artery, and the outlet end is disposed in one of the patient's renal arteries.

While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention, and the appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What Is Claimed Is:

1. Apparatus for locally perfusing one or more kidneys comprising:

a catheter having an inlet end, an outlet end, and a lumen, the inlet end configured for placement in a source of arterial blood, the outlet end having at least a first conduit configured for insertion into a first renal artery; and

means for engaging the first conduit within the first renal artery.

2. The apparatus of claim 1 wherein the inlet end is configured for placement in a patient's left ventricle.

3. The apparatus of claim 1 wherein the outlet end further comprises a second conduit configured for placement in a second renal artery.

4. The apparatus of claim 1 further comprising a drug infusion device.

5. The apparatus of claim 1 further comprising a blood pump

6. The apparatus of claim 1 further comprising a one-way valve that permits blood to flow only from the inlet end to the outlet end.

7. The apparatus of claim 1 wherein the means for engaging comprises an occluder formed from a self-expanding water-swellable material.

8. The apparatus of claim 1 wherein the means for engaging comprises an inflatable member.

9. The apparatus of claim 1 wherein the means for engaging comprises a plurality of ribs or barbs disposed on an exterior surface of the first conduit.

10. The apparatus of claim 1 further comprising a radio-opaque marker band disposed on the first conduit.

11. Apparatus for use in treating congestive heart failure comprising:

a flexible catheter having an inlet end, an outlet end, and a lumen, the inlet end configured for insertion into a source of arterial blood, the outlet end including a first conduit configured for insertion into a patient's renal artery; and

means for engaging an interior surface of a renal artery disposed on the first conduit to retain the first conduit in the patient's renal artery.

12. The apparatus of claim 11 further comprising a drug infusion device.

13. The apparatus of claim 11 further comprising a blood pump.

14. The apparatus of claim 11 further comprising a one-way valve that permits blood to flow only from the inlet end to the outlet end.

15. The apparatus of claim 11 wherein the means for engaging comprises a self-expanding water-swellable material.

16. The apparatus of claim 11 wherein the means for engaging comprises an inflatable member.

17. The apparatus of claim 11 further comprising a radio-opaque marker band disposed on the first conduit.

18. A method of locally perfusing one or more kidneys comprising:

providing a flexible catheter having an inlet end, a lumen, and an outlet end including a first conduit;

advancing the catheter percutaneously and transluminally along a guidewire to dispose the inlet end in a source of arterial blood;

inserting the first conduit into a patient's renal artery; and

engaging the first conduit within the patient's renal artery.

19. The method of claim 18 wherein providing a catheter comprises providing a catheter including a drug infusion device, the method further comprising:

periodically activating the drug infusion device to infuse a drug into blood flowing through the lumen.

20. The method of claim 18 wherein providing a catheter comprises providing a catheter including a blood pump, the method further comprising:

actuating the blood pump to increase a rate of blood flow through the lumen.

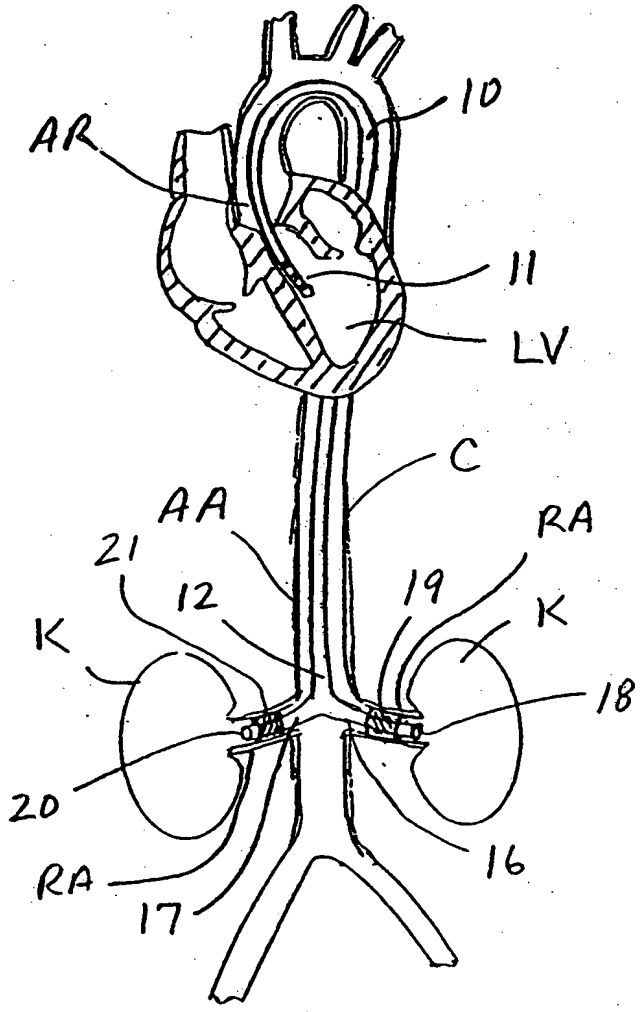
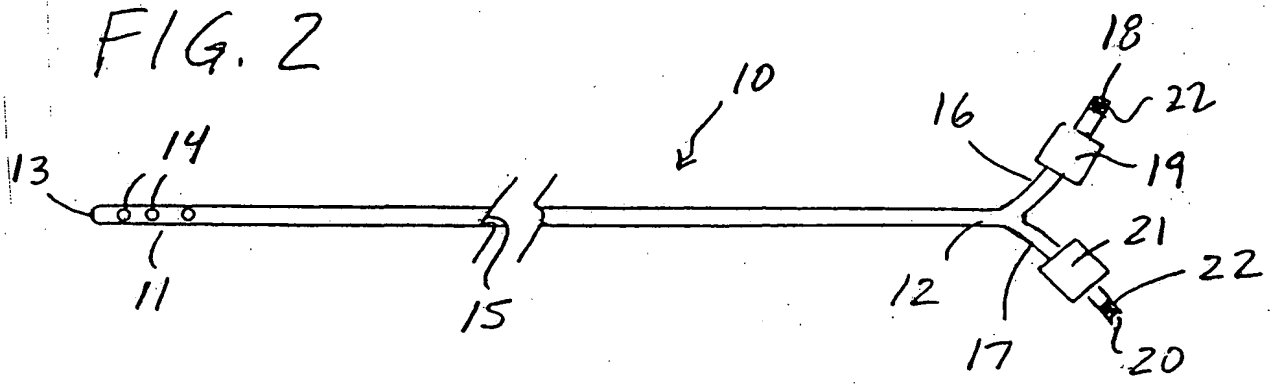


FIG. 1

FIG. 2



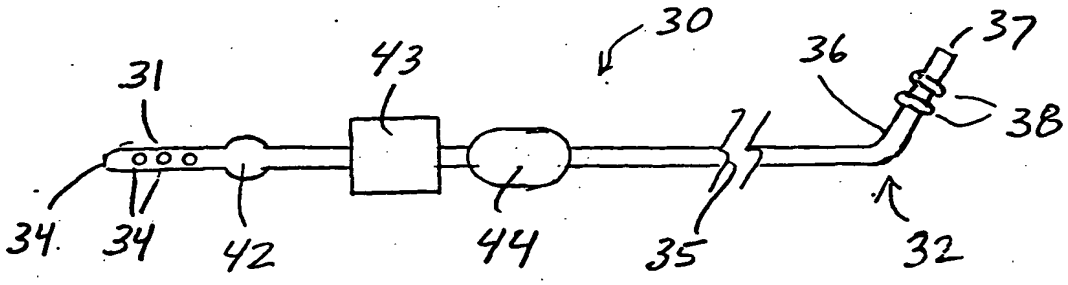


FIG. 3

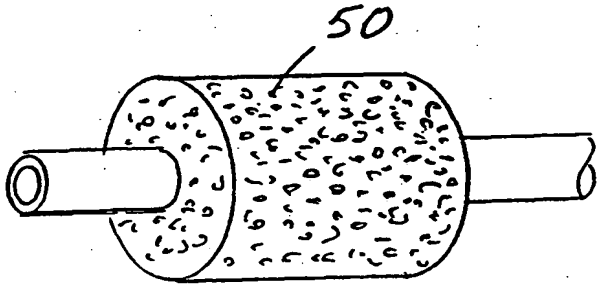


FIG. 4

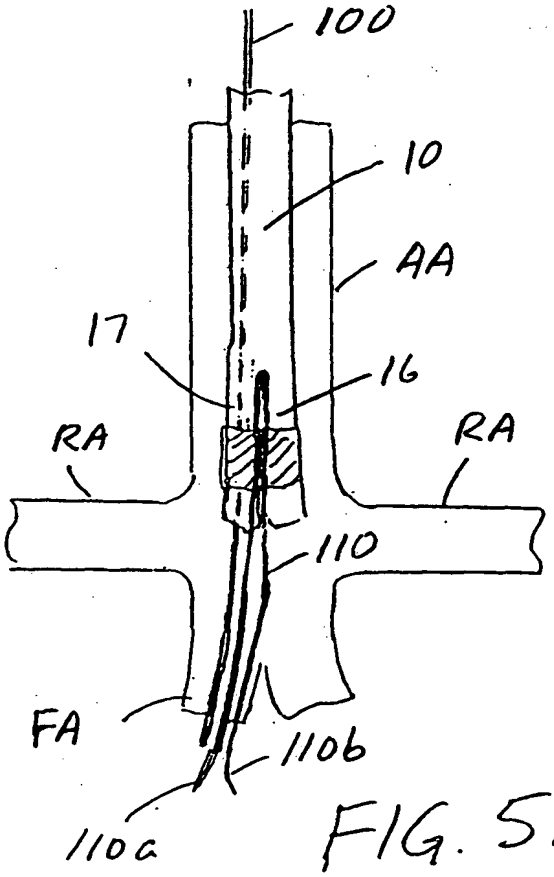


FIG. 5A

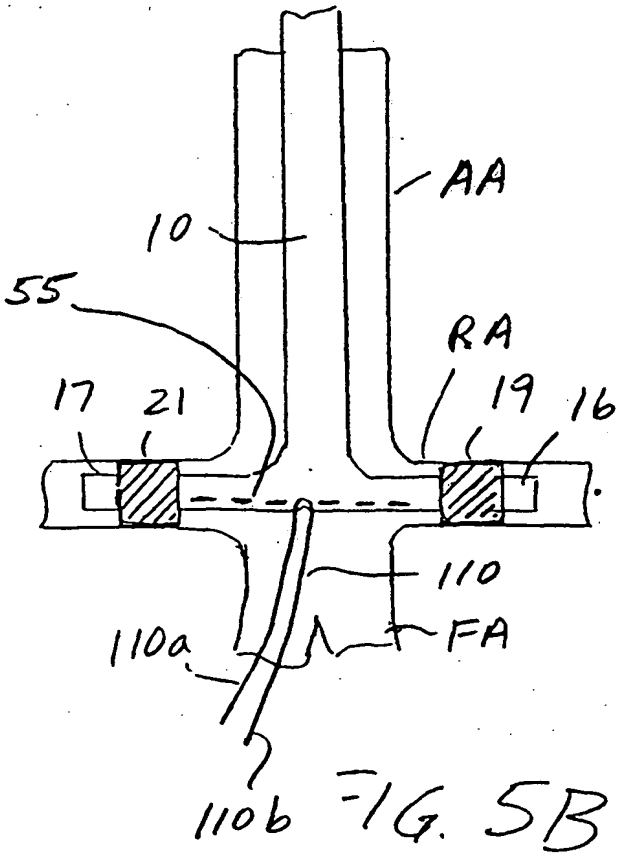


FIG. 5B

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(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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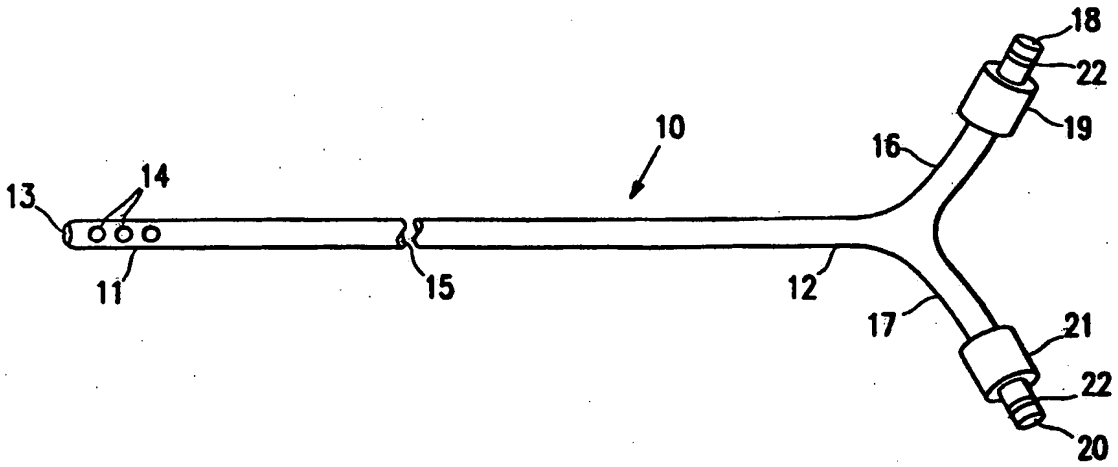
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHODS FOR TREATING CONGESTIVE HEART DISEASE



(57) Abstract: Methods and apparatus are provided for treating congestive heart failure using a catheter having an inlet end configured for placement in the source of arterial blood such as the aorta, left ventricle or a femoral artery, and an outlet end having at least one conduit configured to be placed in the renal arteries. The catheter includes a lumen through which blood passes from the aorta or left ventricle directly to the renal artery, means for engaging the first conduit with renal artery. The means for engaging also may reduce backflow of blood into the abdominal aorta. The catheter preferably is configured to permit percutaneous, transluminal implantation. Methods of using and implanting the catheter are also provided.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 509 428 A (DUNLOP RICHARD W) 23 April 1996 (1996-04-23) column 4, line 39 -column 5, line 50; figures	1,2,8, 11,16
A	US 5 505 701 A (ANAYA FERNANDEZ DE LOMANA EUGE) 9 April 1996 (1996-04-09) abstract; figures	1,11
A	US 5 053 023 A (MARTIN GEOFFREY S) 1 October 1991 (1991-10-01) column 4, line 24 - line 42; figures	1-3,7,11
A	WO 98 52639 A (UNITED STATES SURGICAL CORP) 26 November 1998 (1998-11-26) abstract; figures	1,11

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 October 2000	27/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

1

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INTERNATIONAL SEARCH REPORT

Internat' l Application No
PCT/US 00/00636

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 282 784 A (WILLARD MARTIN R) 1 February 1994 (1994-02-01) abstract; figures	1,11
P,A	WO 99 51286 A (SCIMED LIFE SYSTEMS INC) 14 October 1999 (1999-10-14) page 13, line 7 -page 14, line 8; figures	1,11

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat' Application No
PCT/US 00/00636

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		AT 178805 T	15-04-1999
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		EP 0983104 A	08-03-2000
US 5282784 A	01-02-1994	NONE	
WO 9951286 A	14-10-1999	US 6086527 A	11-07-2000

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(81) Designated States *(national)*: AE, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

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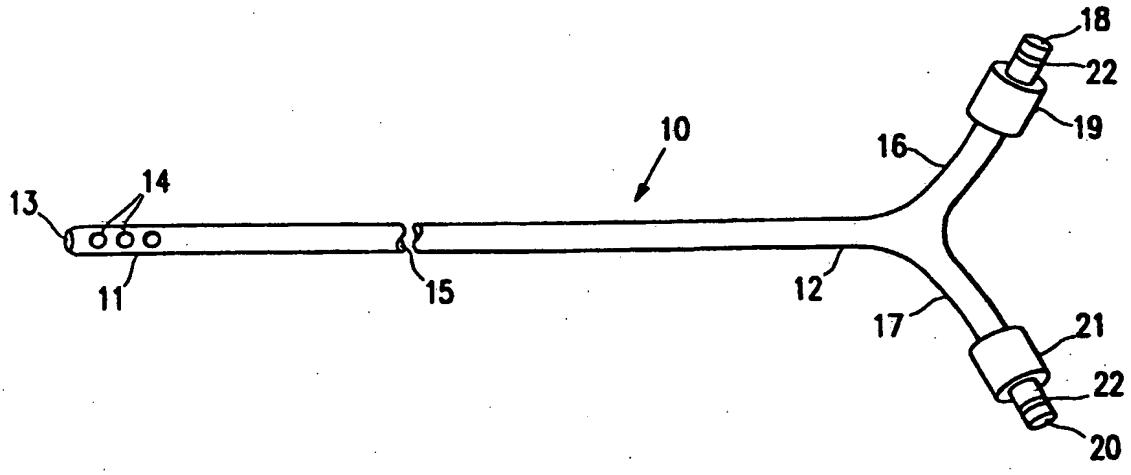
(54) Title: APPARATUS AND METHODS FOR TREATING CONGESTIVE HEART DISEASE



(57) Abstract: Methods and apparatus are provided for treating congestive heart failure using a catheter having an inlet end configured for placement in the source of arterial blood such as the aorta, left ventricle or a femoral artery, and an outlet end having at least one conduit configured to be placed in the renal arteries. The catheter includes a lumen through which blood passes from the aorta or left ventricle directly to the renal artery, means for engaging the first conduit with renal artery. The means for engaging also may reduce backflow of blood into the abdominal aorta. The catheter preferably is configured to permit percutaneous, transluminal implantation. Methods of using and implanting the catheter are also provided.

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(15) Information about Correction:
see PCT Gazette No. 44/2001 of 1 November 2001, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

APPARATUS AND METHODS FOR TREATING CONGESTIVE HEART DISEASE

Field Of The Invention

The present invention relates to apparatus for treating congestive heart disease by providing increased perfusion to the kidneys, thereby enhancing renal function.

Background Of The Invention

It has long been known that cardiac dysfunction induces a series of events that ultimately contribute to congestive heart failure ("CHF"). One such event is a reduction in renal blood flow due to reduced cardiac output. This reduced flow can in turn result in the retention of excess fluid in the patient's body, leading for example, to pulmonary and cardiac edema.

Chapter 62 of Heart Disease: A Textbook of Cardiovascular Medicine, (E. Braunwald, ed., 5th ed. 1996), published by Saunders, Philadelphia, Pennsylvania, reports that for patients with CHF, the fall in effective renal blood flow is proportional to the reduction in cardiac output. Renal blood flow in normal patients in an age range of 20-80 years averages 600 to 660 ml/min/m^2, corresponding to about 14 to 20 percent of simultaneously measured cardiac output. Within a wide spectrum of CHF severity, renal blood flow is depressed to an average range of 250 to 450 ml/min/m^2.

Previously known methods of treating congestive heart failure and deteriorating renal function in patients having CHF principally involve administering drugs, including diuretics that enhance renal function, such as furosemide and thiazide, vasopressors intended to enhance renal blood flow, such as Dopamine, and vasodilators that reduce vasoconstriction of the renal vessels. Many of these drugs, when administered in systemic doses, have undesirable side-effects.

In addition, for patients with severe CHF (e.g., those awaiting heart transplant), mechanical methods, such as hemodialysis or left ventricular assist devices, may be implemented. Mechanical treatments, such as hemodialysis, however, generally have not been used for long-term management of CHF.

Advanced heart failure (''HF'') requires the combination of potent diuretics and severe restriction of salt intake. Poor patient compliance is a major cause of refractoriness to treatment. On the other hand, as renal urine output decreases with reduced renal perfusion, in the event of dehydration, the required diuretic dosages increase.

In view of the foregoing, it would be desirable to provide methods and apparatus for treating and managing CHF without administering high doses of drugs or dehydrating the patient.

It further would be desirable to provide methods and apparatus for treating and managing CHF by improving blood flow to the kidneys, thereby enhancing renal function.

It also would be desirable to provide methods and apparatus for treating and managing CHF that permit the administration of low doses of drugs, in a localized manner, to improve renal function.

It still further would be desirable to provide methods and apparatus for treating and managing CHF using apparatus that may be percutaneously and transluminally implanted in the patient.

Summary of The Invention

In view of the foregoing, it is an object of the present invention to provide methods and apparatus for treating and managing CHF without administering high doses of drugs or dehydrating the patient.

It is another object of this invention to provide methods and apparatus for treating and managing CHF by improving blood flow to the kidneys, thereby enhancing renal function.

It is also an object of this invention to provide methods and apparatus for treating and managing CHF that permit the administration of low doses of drugs; in a localized manner, to improve renal function.

It further is an object of the present invention to provide methods and apparatus for treating and managing CHF using apparatus that may be percutaneously and transluminally implanted in the patient.

These and other objects of the present invention are accomplished by providing a catheter having an inlet end configured for placement in a source of arterial blood, such as the aorta, the left ventricle or a femoral artery, and an outlet end having at least one conduit configured to be placed in a renal artery. The catheter includes a lumen through which arterial blood passes directly into a renal artery. The conduit may include means for engaging an interior surface of the renal artery to retain the conduit in position, and may comprise an occluder that reduces backflow of blood exiting the conduit into the abdominal aorta. The catheter preferably is configured to permit percutaneous, transluminal implantation.

In accordance with the principles of the present invention, high pressure blood passes through the lumen of the catheter during systole and into the conduit disposed in the renal artery. It is expected that blood passing through the catheter will have a higher pressure and higher flow rate than blood reaching the renal artery via the abdominal aorta. This in turn is expected to improve renal function, without administering systemic doses of drugs to improve renal function or renal blood flow. The enhanced renal blood flow is expected to provide a proportional increase in renal function, thereby reducing fluid retention.

In alternative embodiments, the catheter may include first and second conduits for perfusing both kidneys, a one-way valve disposed in the lumen to prevent backflow of blood in the lumen during diastole or a mechanical pump to further enhance the flow of blood through the lumen. Still other embodiments of the catheter may include a drug infusion reservoir that injects a low dose of a drug, e.g., a diuretic or vasodilator, into blood flowing through the

lumen, so that the drug-infused blood passes directly into the kidneys. Still further embodiments may comprise separate catheters to perfuse the left and right kidneys, or may draw arterial blood from a peripheral vessel using an external pump.

Methods of implanting the apparatus of the present invention also are provided.

Brief Description Of The Drawings

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

FIG. 1 is a partial sectional view of a human circulatory system having apparatus constructed in accordance with the present invention implanted therein;

FIG. 2 is a side view of an illustrative embodiment of the apparatus of the present invention;

FIG. 3 is an alternative embodiment of the apparatus of FIG. 2 including a one-way valve, a blood pump and a drug infusion device;

FIG. 4 is a detailed perspective view of an occluder employed on the outlet end of the catheter of FIG. 2; and

FIGS. 5A and 5B are partial sectional views depicting an illustrative method of implanting the catheter of FIG. 2.

Detailed Description Of The Invention

The present invention provides a catheter that may be implanted in patients suffering from congestive heart failure ("CHF") to improve renal blood flow and renal function. In accordance with the principles of the present invention, it is expected that by passing blood from the left ventricle directly to the renal arteries during systole, the blood pressure and flow rate in the kidneys will be increased, resulting in enhanced renal function.

Referring to FIGS. 1 and 2, a first illustrative embodiment of apparatus constructed in accordance with the principles of the present invention is described. Catheter 10 comprises hollow flexible tube having inlet end 11 and outlet end 12. Inlet end 11 includes distal hole 13 and lateral holes 14 that communicate with lumen 15 within catheter 10. Outlet end 12 comprises first and second branch conduits 16 and 17, respectively. Catheter 10 preferably comprises a flexible biocompatible material, such as polyurethane, silicone, or polyethylene.

First branch conduit 16 includes outlet port 18 that communicates with lumen 15, and expandable occluder 19. Likewise, second branch conduit 17 includes outlet port 20 that communicates with lumen 15, and expandable occluder 21. First and second branch conduits 16 and 17 optionally may include radio-opaque marker bands 22 near outlet ports 18 and 20, respectively, to assist in implanting catheter 10.

As depicted in FIG. 1, catheter 10 is implanted in circulatory system C so that inlet end 11 is disposed in left ventricle LV or in the vicinity of aortic root AR, while first and second branch conduits 16 and 17, respectively, are disposed in renal arteries RA. Occluders 19 and 21, described in greater detail hereinafter, engage the walls of the renal arteries and retain first and second branch conduits 16 and 17, respectively in position. The occluders also serve to prevent backflow of high pressure blood exiting through outlet ports 18 and 20 from flowing backwards into abdominal aorta AA. Accordingly, blood entering catheter 10 via distal hole 13 and lateral holes 14 during systole passes directly into renal arteries RA and kidneys K through lumen 15, thereby enhancing renal blood flow and renal function.

Referring now to FIG. 3, an alternative embodiment of the apparatus of the present invention is described. Catheter 30 is similar in construction to catheter 10 of FIG. 1, and includes hollow flexible tube having inlet end 31 and outlet end 32. Inlet end 31 includes distal hole 33 and lateral holes 34 that communicate with lumen 35. Outlet end 32 comprises branch conduit 36 having outlet port 37 configured to be placed in one of the patient's renal arteries. In this

embodiment, the occluder of the embodiment of FIG. 2 is omitted and instead the diameter of the branch conduit 36 is selected to provide a close fit with the renal artery. Engagement means, such as small ribs or barbs 38 also may be disposed on the exterior surface of branch conduit 36 to retain the branch conduit in the renal artery.

Because the renal arteries may branch from the abdominal aorta at different levels, the catheter of FIG. 3 advantageously permits separate catheters to be used to each perfuse only a single kidney. In addition, the inlet end of catheter 30 may be configured to be placed in a peripheral vessel rather than the left ventricle.

Catheter 30 further optionally comprises any one or more of the following components: one-way valve 42, blood pump 43 or drug infusion device 44. While catheter 30 illustratively includes all three of the foregoing components, it is to be understood that any combination of such components advantageously may be employed.

One-way valve 42, if provided, is configured to open during systole to permit blood to flow through lumen 35 from left ventricle LV towards the renal artery RA, but closes during diastole to prevent the left ventricle from drawing blood in the opposite direction.

Blood pump 43, if provided, may comprise an implantable blood pump, such as are known in the art, and serves to enhance renal blood flow in those patients suffering from severe cardiac dysfunction. Alternatively, where the inlet end of catheter 30 is configured to be placed in a peripheral vessel, blood pump 30 advantageously may comprise an external blood pump, such as are known in the art.

Drug infusion device 44, if provided, preferably comprises an implantable infusion device, such as are known in the art (e.g., for chelation therapy), and periodically infuses low doses of therapeutic agents into blood flowing through lumen 35. Because the infused drugs are delivered directly into

the kidneys, smaller doses may be employed, while achieving enhanced therapeutic action and fewer side-effects.

With respect to FIG. 4, an illustrative embodiment of occluder 50 suitable for use with the catheter of FIGS. 1 and 2 is described. In one embodiment, occluder 50 comprises a low density, biocompatible sponge-like material that may be compressed to a small thickness, and that absorbs and expands when exposed to body fluid. In particular, occluder 50 preferably is compressed to a small thickness and then mounted on the branch conduit so that, when the occluder is deployed in a renal artery, it swells and engages the interior of the renal artery.

Occluder 50 therefore serves to retain the branch conduit in position in a renal artery, and also reduces backflow of blood from the renal artery into the abdominal aorta. Alternatively, occluder 50 may comprise an inflatable member that is inflated and then sealed via a lumen (not shown) extending out of the patient's femoral artery. As a yet further alternative, occluder 50 may comprise a self expanding hydrogel material that swells when exposed to body fluids to accomplish the functions described hereinabove.

While occluder 50 of FIG. 4 illustratively has an annular shape, it should be understood that other shapes may be employed. For example, occluder 50 may be configured to only partially surround the branch conduit, and may provide only a partial seal with the interior surface of the renal artery. For example, depending upon the relative sizes of the branch conduit and the renal artery, and how far the branch conduit extends into the renal artery, occluder 50 may be omitted altogether.

Referring now to FIGS. 1, 5A and 5B, percutaneous, transluminal implantation of the apparatus of FIG. 2 is described. First, guidewire 100 is inserted in a retrograde manner through abdominal aorta AA via an access site in femoral artery FA until the tip of the guidewire is disposed in the left ventricle, e.g., as determined by fluoroscopy. Catheter 10 is then advanced along guidewire 100, for example, using a push tube (not shown) disposed on guidewire 100, with

first and second branch conduits 16 and 17 folded side-by-side. Filament 110 is looped through a small opening at the bifurcation of the first and second branch conduits 16 and 17, so that the free ends 110a and 110b of loop 110 may be manipulated by the surgeon.

As depicted in FIG. 5A, catheter 10 is pushed in a distal direction so that outlet ports 18 and 20 of outlet end 12 clear the renal arteries, and guidewire 100 is withdrawn. Filament 110 then is pulled in the proximal direction so that the ends of the first and second branch conduits move into renal arteries **RA**, as illustrated in FIG. 5B. Strand 55 of an elastic, high strength material, such as a nickel-titanium alloy, may be embedded in the wall of catheter 10 in the bifurcation to ensure that the first and second conduits open outwardly when catheter 10 is pulled in a proximal direction by filament 110.

Once the position of first and second branch conduits 16 and 17 is confirmed, for example, by observing the location of radio-opaque markers 22 (see FIG. 2) with a fluoroscope, occluders 19 and 21 expand to engage the interior surfaces of the renal arteries. Expansion of the occluders may be accomplished either by holding the occluders in place while they expand (if self-expanding) or, if the occluders are inflatable, by injecting a suitable inflation medium.

Filament 110 then may be pulled completely through the opening in the bifurcation of catheter 10, leaving catheter 10 implanted in position. It is expected that the opening needed to accommodate filament 110 will result in negligible loss of blood through the opening once filament 110 has been withdrawn. Alternatively, or in addition, additional guidewires (not shown) may be disposed through first and second branch conduits to assist in placing the first and second branch conduits in renal arteries **RA**.

The foregoing methods may be readily adapted to implant two catheters of the type illustrated in FIG. 3, so that the branch conduit of each catheter perfuses a separate kidney. In addition, for acute treatment of CHF, the catheter of FIG. 3 (including an external blood pump) may be placed so that the

inlet end is disposed in a patient's femoral artery, and the outlet end is disposed in one of the patient's renal arteries.

While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention, and the appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What Is Claimed Is:

1. Apparatus for locally perfusing one or more kidneys comprising:

a catheter having an inlet end, an outlet end, and a lumen, the inlet end configured for placement in a source of arterial blood, the outlet end having at least a first conduit configured for insertion into a first renal artery; and

means for engaging the first conduit within the first renal artery.

2. The apparatus of claim 1 wherein the inlet end is configured for placement in a patient's left ventricle.

3. The apparatus of claim 1 wherein the outlet end further comprises a second conduit configured for placement in a second renal artery.

4. The apparatus of claim 1 further comprising a drug infusion device.

5. The apparatus of claim 1 further comprising a blood pump

6. The apparatus of claim 1 further comprising a one-way valve that permits blood to flow only from the inlet end to the outlet end.

7. The apparatus of claim 1 wherein the means for engaging comprises an occluder formed from a self-expanding water-swellable material.

8. The apparatus of claim 1 wherein the means for engaging comprises an inflatable member.

9. The apparatus of claim 1 wherein the means for engaging comprises a plurality of ribs or barbs disposed on an exterior surface of the first conduit.

10. The apparatus of claim 1 further comprising a radio-opaque marker band disposed on the first conduit.

11. Apparatus for use in treating congestive heart failure comprising:

a flexible catheter having an inlet end, an outlet end, and a lumen, the inlet end configured for insertion into a source of arterial blood, the outlet end including a first conduit configured for insertion into a patient's renal artery; and

means for engaging an interior surface of a renal artery disposed on the first conduit to retain the first conduit in the patient's renal artery.

12. The apparatus of claim 11 further comprising a drug infusion device.

13. The apparatus of claim 11 further comprising a blood pump.

14. The apparatus of claim 11 further comprising a one-way valve that permits blood to flow only from the inlet end to the outlet end.

15. The apparatus of claim 11 wherein the means for engaging comprises a self-expanding water-swellable material.

16. The apparatus of claim 11 wherein the means for engaging comprises an inflatable member.

17. The apparatus of claim 11 further comprising a radio-opaque marker band disposed on the first conduit.

18. A method of locally perfusing one or more kidneys comprising:

providing a flexible catheter having an inlet end, a lumen, and an outlet end including a first conduit;

advancing the catheter percutaneously and transluminally along a guidewire to dispose the inlet end in a source of arterial blood;

inserting the first conduit into a patient's renal artery; and

engaging the first conduit within the patient's renal artery.

19. The method of claim 18 wherein providing a catheter comprises providing a catheter including a drug infusion device, the method further comprising:

periodically activating the drug infusion device to infuse a drug into blood flowing through the lumen.

20. The method of claim 18 wherein providing a catheter comprises providing a catheter including a blood pump, the method further comprising:

actuating the blood pump to increase a rate of blood flow through the lumen.

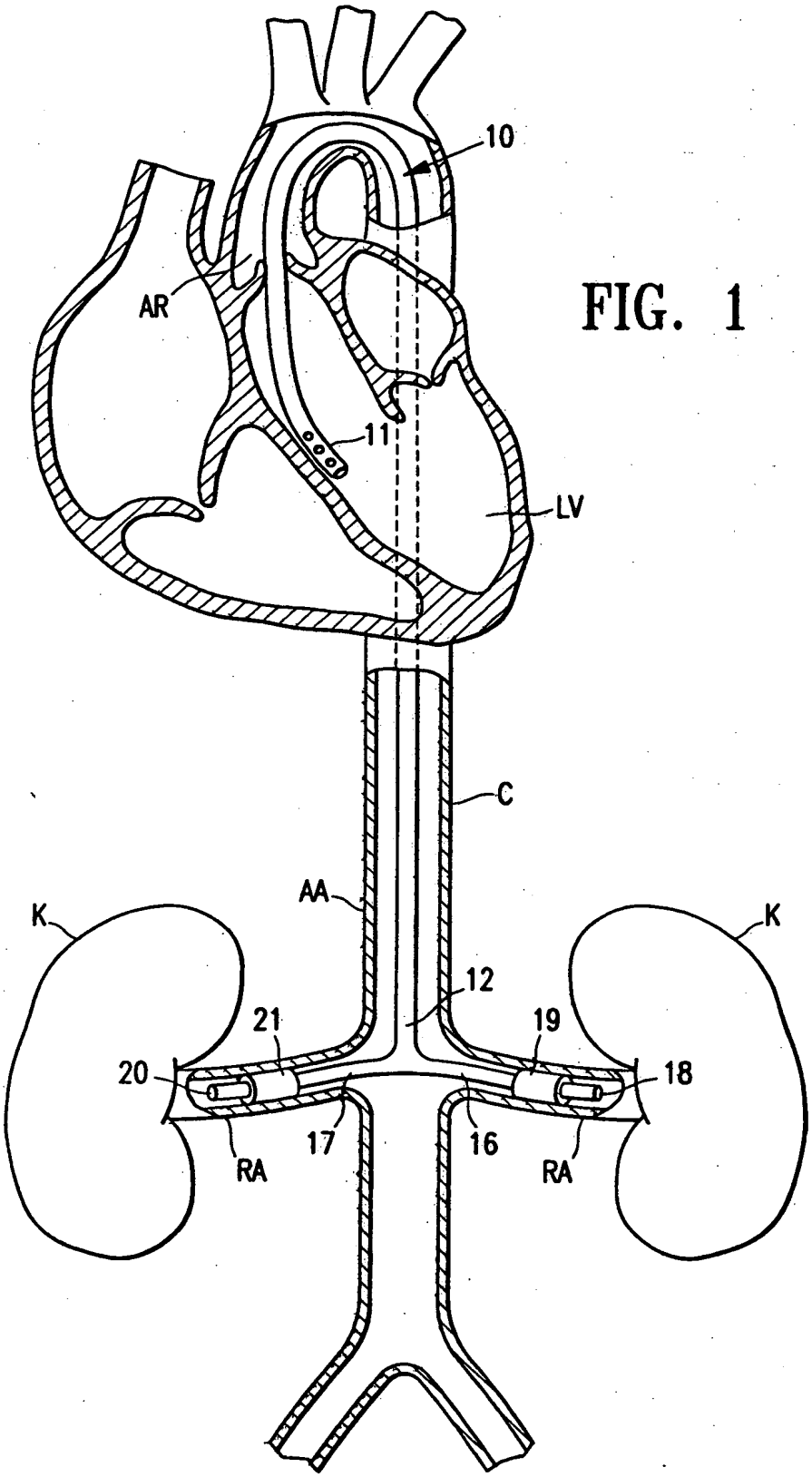


FIG. 1

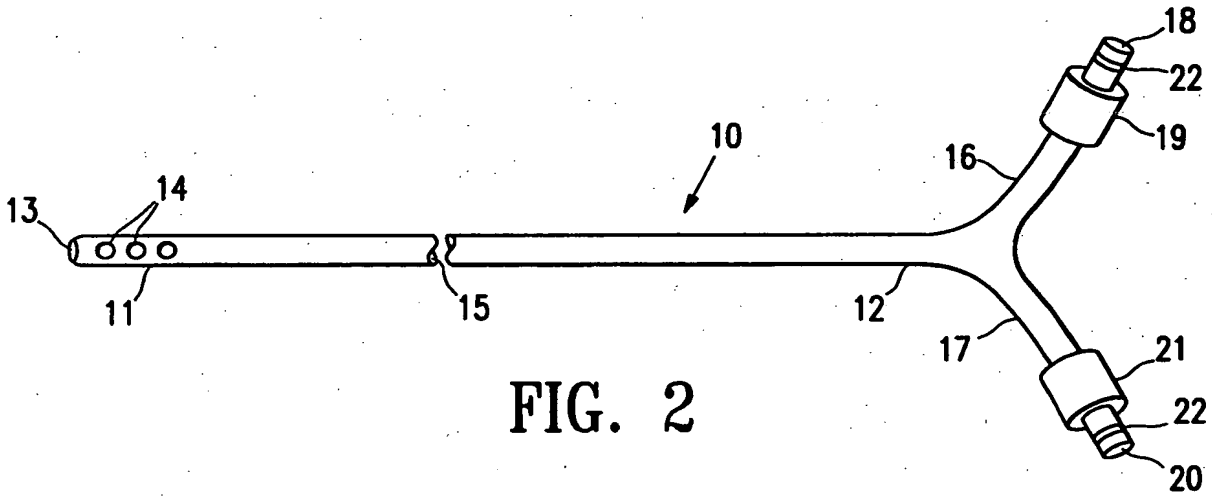


FIG. 2

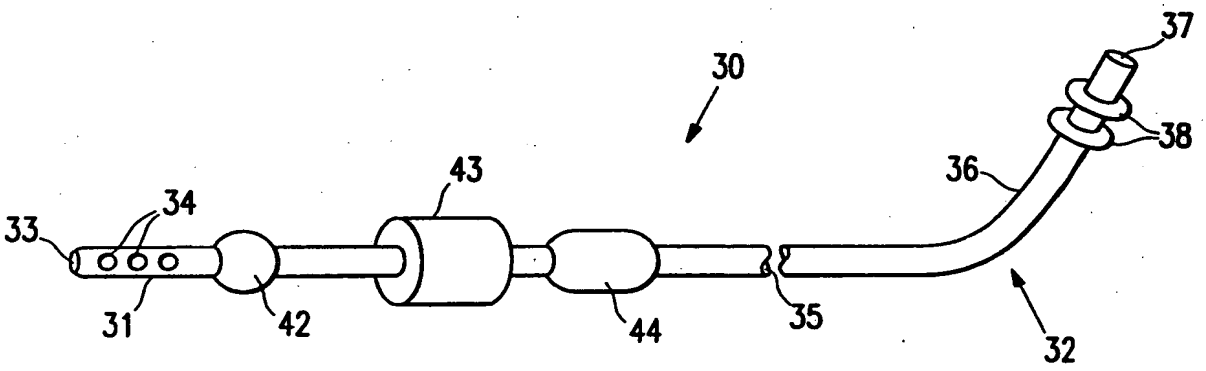


FIG. 3

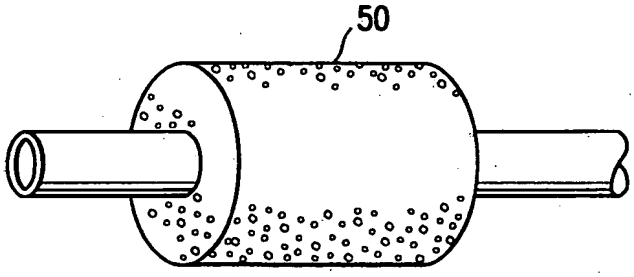


FIG. 4

FIG. 5A

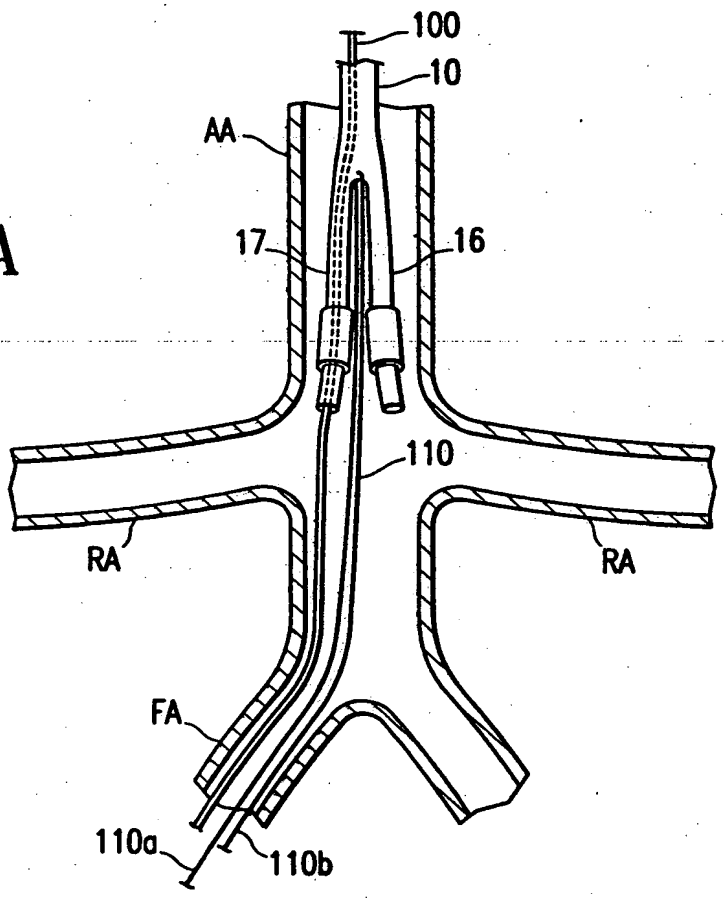
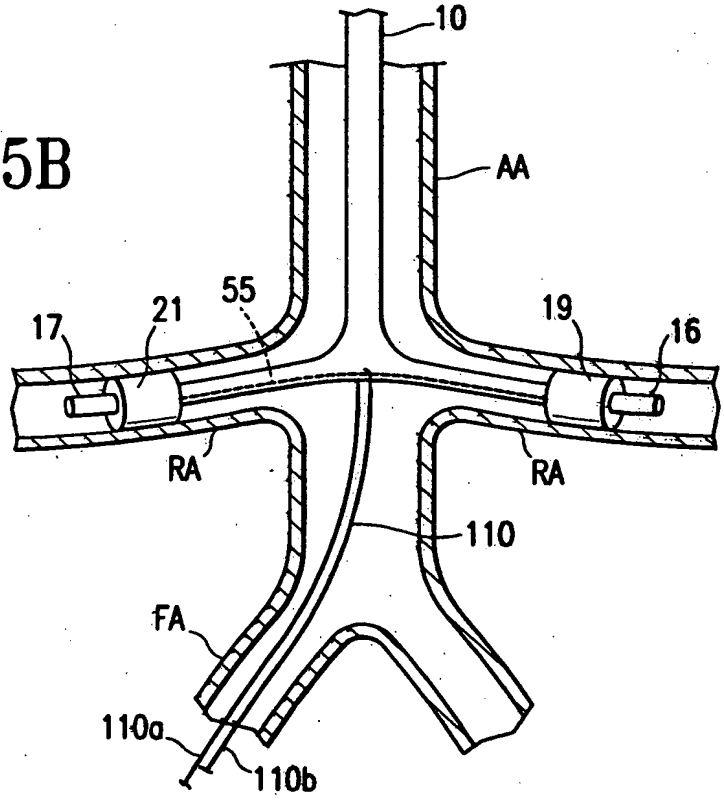


FIG. 5B



INTERNATIONAL SEARCH REPORT

Internat l Application No
PCT/US 00/00636

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 509 428 A (DUNLOP RICHARD W) 23 April 1996 (1996-04-23) column 4, line 39 -column 5, line 50; figures	1,2,8, 11,16
A	US 5 505 701 A (ANAYA FERNANDEZ DE LOMANA EUGE) 9 April 1996 (1996-04-09) abstract; figures	1,11
A	US 5 053 023 A (MARTIN GEOFFREY S) 1 October 1991 (1991-10-01) column 4, line 24 - line 42; figures	1-3,7,11
A	WO 98 52639 A (UNITED STATES SURGICAL CORP) 26 November 1998 (1998-11-26) abstract; figures	1,11

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 October 2000	27/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

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INTERNATIONAL SEARCH REPORT

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PCT/US 00/00636

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A	US 5 282 784 A (WILLARD MARTIN R) 1 February 1994 (1994-02-01) abstract; figures	1,11
P,A	WO 99 51286 A (SCIMED LIFE SYSTEMS INC) 14 October 1999 (1999-10-14) page 13, line 7 -page 14, line 8; figures	1,11

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Ir. .nation on patent family members

Internat' ' Application No
PCT/US 00/00636

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		CA 2136407 A	23-05-1995
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WO 9951286 A	14-10-1999	US 6086527 A	11-07-2000

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
26842-5000PC		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 00/ 00636	11/01/2000	11/01/1999

Applicant

THERAPEE ADVANCED MEDICAL INNOVATION, LTD.

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/00636

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 509 428 A (DUNLOP RICHARD W) 23 April 1996 (1996-04-23) column 4, line 39 -column 5, line 50; figures	1,2,8, 11,16
A	US 5 505 701 A (ANAYA FERNANDEZ DE LOMANA EUGE) 9 April 1996 (1996-04-09) abstract; figures	1,11
A	US 5 053 023 A (MARTIN GEOFFREY S) 1 October 1991 (1991-10-01) column 4, line 24 - line 42; figures	1-3,7,11
A	WO 98 52639 A (UNITED STATES SURGICAL CORP) 26 November 1998 (1998-11-26) abstract; figures	1,11

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 October 2000	27/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/00636

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 282 784 A (WILLARD MARTIN R) 1 February 1994 (1994-02-01) abstract; figures	1,11
P,A	WO 99 51286 A (SCIMED LIFE SYSTEMS INC) 14 October 1999 (1999-10-14) page 13, line 7 -page 14, line 8; figures	1,11

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/00636

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/00636

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5509428 A	23-04-1996	NONE	
US 5505701 A	09-04-1996	ES 2077519 A	16-11-1995
		AT 178805 T	15-04-1999
		CA 2136407 A	23-05-1995
		DE 69417847 D	20-05-1999
		EP 0654283 A	24-05-1995
		JP 7255836 A	09-10-1995
US 5053023 A	01-10-1991	CA 1326620 A	01-02-1994
		EP 0370158 A	30-05-1990
		JP 2116380 A	01-05-1990
WO 9852639 A	26-11-1998	AU 7388698 A	11-12-1998
		EP 0983104 A	08-03-2000
US 5282784 A	01-02-1994	NONE	
WO 9951286 A	14-10-1999	US 6086527 A	11-07-2000